NIH can support research that proposes to use human embryonic stem cells that meet the criteria established by President Bush on August 9, 2002. This Reviewer Guidance is provided because there are a number of issues that may arise during the review of these applications that are rather unique and specific to human embryonic stem cell research.

Reviewer Guidance:

Streamlined Review: Effective 2006/05, all applications proposing the use of human embryonic stem cells may be subjected to Streamlined Review by initial review groups.

Issues regarding an applicant's limited preliminary data: Because this is such a new field of study, investigators may not have had previous access to human embryonic stem cell lines. Also, you may have questions about the feasibility of the proposed research. In such cases, the scientific review should focus on determining whether the investigator has included credible plans for using these cells. The research plan may include discussion about the investigator's experiences in research using embryonic stem cell lines of other species or other types of stem cells, or a plan to acquire the necessary skills and technical abilities. Frequently asked questions that provide additional information on this issue: http://stemcells.nih.gov/info/faqs.asp.

Issues regarding institutional review board (IRB) approval: Under most circumstances these activities will not involve human subjects and, therefore, will not require IRB review or approval. Basic research using cell lines from which the identity of the donor(s) of the embryo that yielded the cell lines cannot readily be ascertained by the investigator, is not considered human subjects research, is not governed by 45 CFR 46 or 21 CFR 50 & 56, and IRB review is not required. Research using cell lines that are identifiable with a donor(s) of the embryo, including cell lines that retain links to coded information that would allow identification of the donor(s) may require an IRB review. Recent guidance by the Office of Human Research Protections addresses conditions when identifying information exists - http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf (Adobe Acrobat Reader is required for this file).

Issues regarding an investigator's access to a particular stem cell line (e.g., materials transfer agreements or intellectual property rights agreements): These issues are not a component of the scientific review and will be handled by NIH grants administrative practices. If you believe such issues are present in an application you are reviewing, they should be included as an administrative note, but are not a part of and should not affect the scientific evaluation. It is commonplace that programmatic issues involving, for example, budget, special authorizations and clearances, and intellectual property, are managed by NIH Institute and Center program officials. Under these circumstances, NIH grants administration expertise is used to assure that the necessary agreements and materials are in place prior to making an award.

Additional Information:

Information about what constitutes an embryonic stem cell line and related background materials about stem cell research can be found at the following resources: http://stemcells.nih.gov/info/basics/ and http://stemcells.nih.gov/info/scireport/

Guidance has been issued by NIH about what kinds of research activities can be conducted with human embryonic stem cell research using federal funds. This guidance is found at http://stemcells.nih.gov/policy/ In addition, there are certain areas of research that are not allowed and these points are explained at http://stemcells.nih.gov/info/faqs.asp#ineligible

The NIH Human Embryonic Stem Cell Registry is available at the NIH website: http://stemcells.nih.gov/research/registry/ This registry provides information, including a unique identifying code, about each human embryonic stem cell line that is eligible for research to be conducted with federal funding. The grant application must reference the NIH code for the human ES cell line involved. It is suggested, but not required, that the NIH code be provided in the research plan abstract. Applicants are encouraged to describe the proposed use of these cells in the abstract.

Revised 11-25-05

Posted 12-02-05